ABSTRACT

Validation of HPLC For Comparative Dissolution Test of Piroxicam Tablet

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The purpose of this study was to obtain a valid analysis method for in-vitro comparative dissolution test of piroxicam tablets using HPLC. The chromatographic separation was achieved using Lichrospher 100 RP-18 column (250 mm x 4 mm i.d., 5 μm particle size). The isocratic mobile phase was methanol: pH 4.0 phosphate buffer (45:55; v/v) at a flow rate of1,2 mL/min and column temperature of 40°C. The analysis determination were performed using UV-Vis detector at λ of353 nm. The simulated samples with three different dissolution media at pH of 1,2; 4,5 and 6,8. The sample volume injected was 20 μL. The method showed linear relationship with regression equation of y= 28765.95x-398058,3 with r = 0.9998, y = 31413.18x-310086.9 with r = 0.9990 and y = 25295.31x-385507.2 with r = 0.9990 at pH 1,2, pH4,5 and pH 6,8, respectively. The method showedprecision, with a relative standard deviation (RSD) smaller than 2%. The accuracy test by spiked placebo procedure obtained good *recovery* i.e. 100,21; 100,13 and 100,50 respectively. The HPLC condition in this study is suitable for determination of dissolution profiles of piroxicam in tablets.

Keywords : Method validation, HPLC, compartive dissolution, piroxicam